2018 Current Fiscal Year Report: Vaccines and Related Biological Products Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Vaccines and Related Biological Products Advisory Committee	1041

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	12/31/2017	12/31/2019	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	12/31/1979	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 2 **Other Activities** 0 **17d. Total** 4

Meetings and Dates

Purpose	Start	End
On October 4, 2017, the VRBPAC met in an open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2018 southern hemisphere influenza season. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm	10/04/2017	10/04/2017
On November 7, 2017, the committee met in an open session to discuss and make recommendations on the clinical development plan for Pfizer's investigational Staphylococcus aureus vaccine intended for pre-surgical prophylaxis in elective orthopedic surgical populations.	11/07/2017	11/07/2017

On March 1, 2018, under Topic I, CBER's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session to hear an overview of the research program in the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI), Division of Bacterial, Parasitic and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER), FDA. Also on March 1, 2018, under Topic II, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2018-2019 influenza season. FDA intends to make background material available to the public no later than 2 business days before the meeting.	03/01/2018 - 03/01/2018
On May 17, 2018, under Topic I, the Center for Biologics Evaluation and Research's (CBER) VRBPAC met in open session to discuss approaches for demonstrating effectiveness of group B streptococcus (GBS) vaccines intended for use in pregnant women to protect the newborn infant. Also on May 17, 2018, under Topic II, the committee met in open session to hear an overview of the research program in the Laboratory of Respiratory Viral Diseases (LRVD), Division of Viral Products, Office of Vaccines Research and Review, CBER, FDA.	05/17/2018 - 05/17/2018

Number of Committee Meetings Listed: 4

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$21,348.00	$44,295.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$499,333.00	$445,356.00
18a(4). Personnel Pmts to Non-Member Consultants	$8,712.00	$15,312.00
18b(1). Travel and Per Diem to Non-Federal Members	$20,080.00	$25,555.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$20,110.00	$14,574.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$147,694.00	$150,598.00
18d. Total	$717,277.00	$695,690.00
19. Federal Staff Support Years (FTE)	2.89	2.35

20a. How does the Committee accomplish its purpose?

October 4, 2017 – The Committee met in open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2018 southern hemisphere influenza season.Agency Action: The recommendations made by the Vaccines and Related Biological Products Advisory Committee (VRBPAC) were considered in the Agency's decision regarding regulatory actions on influenza vaccine strains to include in the 2017-2018 formulation for the southern hemisphere influenza season. November 7, 2017 - The Committee met in open session to discuss and make recommendations on the clinical development plan for Pfizer's investigational Staphylococcus aureus vaccine intended for pre-surgical prophylaxis in elective orthopedic surgical populations.Agency Action: The FDA considered the advice of the committee regarding Pfizer's Staphylococcus aureus vaccine in future communications with the sponsor regarding their clinical development plan. March 1, 2018, Topic I, the Committee met in open session to hear an overview of the research program in the Laboratory of Mucosal Pathogens and Cellular Immunology, Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and

Review, FDA. Topic II, the Committee met in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2018-2019 influenza season. Agency Action: In July 2018, CBER/OVRR approved strain change supplements for licensed influenza vaccines to include in the 2018-2019 formulation for the northern hemisphere influenza season recommended by the VRBPAC Committee. May 17, 2018, Topic I, the Committee met in open session to discuss approaches for demonstrating effectiveness of group B streptococcus (GBS) vaccines intended for use in pregnant women to protect the newborn infant. Topic II, the Committee met in open session to hear an overview of the research program in the Laboratory of Respiratory Viral Diseases, Division of Viral Products, Office of Vaccines Research and Review. Agency Action: Recommendations made during this meeting informed regulatory considerations and dialogue with sponsors regarding ongoing clinical development of GBS vaccines.

20b. How does the Committee balance its membership?
Members are experts in immunology, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. One member is technically qualified and identified with consumer interests and one non-voting member represents the point of view of industry.

20c. How frequent and relevant are the Committee Meetings?
Four meetings (two open, and two partially closed) were held in FY 2018. The Committee receives information regarding the scope and mission of the research programs from the Office of Vaccines Research and Review. All discussions are related to components of the Strategic Plan and FDA's Critical Path to New Medical Products. For FY 2019, 5 open meetings and 1 partially closed meeting are planned.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
Members of the committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions made and helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?
N/A

21. Remarks

No reports are required for this committee.

Designated Federal Officer

Serina A Hunter-Thomas Center for Biologics Evaluation and Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Edwards, Kathryn	02/01/2015	01/31/2019	Vanderbilt University School of Medicine	Special Government Employee (SGE) Member
El Sahly, Hana	06/10/2016	01/31/2020	Baylor College of Medicine	Special Government Employee (SGE) Member
Englund, Janet	02/01/2014	01/31/2018	Director, Pediatric Transplant Infectious Diseases, Seattle Children's Hospital	Special Government Employee (SGE) Member
Greenberg, David	02/01/2016	01/31/2020	Sanofi Pasteur USA	Representative Member
Janes, Holly	06/10/2016	01/31/2020	Associate Member, Fred Hutchinson Cancer Research Center	Special Government Employee (SGE) Member
Kotloff, Karen	02/01/2014	01/31/2018	Associate Director for Clinical Research and Chief, Center for Vaccine Development, University of Maryland School of Medicine	Special Government Employee (SGE) Member
Levine, Myron	05/09/2018	01/31/2022	Medical Physician and Professor	Special Government Employee (SGE) Member
Levy, Ofer	02/01/2015	01/31/2019	Boston Children’s Hospital, Harvard Medical School	Special Government Employee (SGE) Member
Long, Sarah	02/01/2014	01/31/2018	Chief, Section of Infectious Diseases, St. Christopher's Hospital for Children	Special Government Employee (SGE) Member
Lynfield, Ruth	04/30/2014	01/31/2018	State Epidemiologist and Medical Director, Minnesota Department of Health	Special Government Employee (SGE) Member
McInnes, Pamela	05/13/2016	01/31/2019	National Center for Advancing Translational Sciences (NCATS)	Ex Officio Member
Monto, Arnold	02/01/2016	01/31/2020	University of Michigan School of Public Health	Special Government Employee (SGE) Member
Moore, Patrick	02/01/2014	01/31/2018	Director, Cancer Virology Program, University of Pittsburgh Cancer Institute	Special Government Employee (SGE) Member
Offit, Paul	02/01/2018	01/31/2022	Professor of Pediatrics	Special Government Employee (SGE) Member
Sawyer, Mark	02/01/2014	01/31/2018	Professor of Clinical Pediatrics, Univ of California, San Diego	Special Government Employee (SGE) Member
Shane, Andrea	02/01/2018	01/31/2022	Associater Professor of Pediatrics	Special Government Employee (SGE) Member

Spearman, Paul	05/09/2018	01/31/2022	Medical Physician and Professor	Special Government Employee (SGE) Member
Toubman, Sheldon	08/16/2017	01/31/2021	Consumer Representative, Lawyer	Special Government Employee (SGE) Member
Wharton, Melinda	05/13/2016	01/31/2020	Director, Immunization Services Division, Centers for Disease Control and Prevention	Ex Officio Member

Number of Committee Members Listed: 19

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tabacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Vaccines and Related Biological Products Advisory Committee supports FDA's mission and strategic action plan by reviewing and evaluating available data relating to the safety and effectiveness of vaccines and related biological products, which are intended for, use in the prevention, treatment, or diagnosis of human diseases. The Committee also considers the quality and relevance of FDA's research programs which provides scientific support for the regulation of these products. The Committee supports FDA's mission by using science-based efficient risk management in all of its activities. The Committee recommendations provide the most health promotion and protection at the least cost for the public. This Committee assists the Agency in ensuring timely, high quality, cost-effective processes for review of new technologies/pre-market submissions, effective communication and working relationships with stakeholders to enhance U.S. and global health outcomes, accurately analyzing risks associated with medical products, facilitating the development and availability of medical countermeasures to limit the effects of a terrorist attack on the civilian and military populations, protecting the safety and security of biologics, especially vaccines, all key components of FDA's strategic plan objectives.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓

Effective grant making	☐
Improved service delivery	☐
Increased customer satisfaction	☑
Implementation of laws or regulatory requirements	☑
Other	☐

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

The utilization of the Vaccines and Related Biological Products Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

100

Number of Recommendations Comments

The Committee made approximately 100 recommendations from FY2003 through FY2018. See 20a of the Annual Report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

80%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

20%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

The Agency usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve a new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☐
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A